UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/381,344 | 09/20/99 | SEEMANN G | 2481.1640 |

HM22/1219

FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
1300 I STREET NW
FRANKLIN SQUARE BLDG SUITE 700
WASHINGTON DC 20005-3315

| EXAMINER | |
|---|---|
| LEE, G | |
| ART UNIT | PAPER NUMBER |
| 1632 | 3 |

DATE MAILED: 12/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

File

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/381,344 | Seemann et al. |
| **Examiner** | **Group Art Unit** |
| Gai (Jennifer) Mi Le | 1632 |

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

☒ Claim(s) 1-9 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-9 are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: A specific species of $R^1$, $R^2$, $R^3$ and X wherein species of the Markush Group are listed in claims 1 and 2.

Claim 1 is directed to a method for increasing the tolerance of a mammal to transgenic cells, after discontinuing concomitant immunosuppressant therapy, by administering a pharmaceutical or pharmaceutical combination comprising p15-deoxyspergualin, anti-T-cell antibody, corticosteriod, azathioprine, methotrexate or a compound of the formula (I) or (II) or an optionally stereoisomeric form of the compound of the formula I or II and/or a physiologically tolerable salt of the compound of the formula I wherein:

Applicant is required to select one of the following species: pharmaceutical combination comprising p15-deoxyspergualin, anti-T-cell antibody, corticosteriod, azathioprine, methotrexate or a compound of the formula (I) or (II) or an optionally stereoisomeric form of the compound of the formula I or II and/or a physiologically tolerable salt of the compound of the formula I **and** one of the following species for each $R^1$, $R^2$, $R^3$ and X:

$R^1$'s species are: a) $(C_1\text{-}C_4)$-alkyl

b) $(C_3\text{-}C_5)$-cycloalkyl

c) $(C_2$-$C_6)$-alkenyl or

d) $(C_2$-$C_6)$-alkynyl

$R^2$ 's species are: a) $-CF_3$

b) $-O-CF_3$

c) $-S-CF_3$

d) -OH

e) $-NO_2$

f) halogen

g) benzyl

h) phenyl

i) -O-phenyl

k) -CN or

l) -O-phenyl, mono- or polysubstituted by

1)$(C_1$-$C_4)$-alkyl

2) halogen

3) $-O-CF_3$ or

4) $-O-CH_3$

$R^3$ 's species are: a) $(C_1$-$C_4)$-alkyl

b) halogen or

c) a hydrogen atom and

X's species are: a) -CH group or

b) a nitrogen atom

Claim 2 is directed to the method as claimed in claim 1, wherein the pharmaceutical comprises the compound of the formula I and/or II or an optionally stereoisomeric form of the compound of the formula I or II and/or a salt of the compound of the formula I wherein: Applicant is required to select one of the following species for claim 2: one of the following species for each $R^1$, $R^2$, $R^3$ and X.

$R^1$'s species are: a) methyl

b) cyclopropyl or

c) $(C_3$-$C_5)$-alkynyl

$R^2$'s species are: $-CF_3$ or -CN,

$R^3$'s species are: a hydrogen atom or methyl, and

X's specie is: a -CH group.

Applicant is required to select one of the following species for claim 3: pharmaceutical comprises N-(4-trifluoromethylphenyl)-5-mehtylisoxazole-4-carboxamide, N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide, 2-cyano-3-cyclopropyl-3-hydroxy acrylic acid (4-cyanophenyl)amide or N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxyhept-2-en-6-ynecarboxamide.

Applicant is required to select one of the following species for claim 7: hereditary disorders such as cystic fibrosis, familial hypercholesterolemia, hemophilia, sickle cell anemia;

of nerve and brain disorders such as Parkinson's, Alzheimer's or Kreuzfeld-Jakob syndrome; of rheumatic disorders, osteoarthritis, osteoporosis or arthrosis, of phenylketonuria; of metabolic disorders; of inflammations; of carcinomatous disorders; of infectious disorders; or of hormone and growth disorders.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species of claim 1 fails to have common significant structure.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gai (Jennifer) Mi Lee, whose telephone number is 703-306-5881. The examiner can normally be reached on Monday-Thursday from 8:30 to 5:00 (EST). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on 703-305-6608. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

**Gai (Jennifer) Lee**
**Patent Examiner**
**Art Unit 1600**

Karen M. Hauda
KAREN M. HAUDA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600